

**REMARKS**

Claims 1, 3 and 5 through 8 and new Claims 9 and 10 are pending in the application.

Claims 1, 5 and 6 have been amended to reflect advantageous embodiments in which an active-ingredient- containing drug, food or cosmetic-containing coating is heated to approximately 40 to 100 °C and the heated coating is applied onto a carrier material via synchronized rollers. Support for this amendment can be found in the Application-as-filed, for example on Page 1, lines 13 through 25.

Claim 5 has been further amended to remove a redundant phrase.

Claims 9 and 10 have been added to complete the record for examination and highlight advantageous embodiments of the invention. Claims 9 and 10 are directed to advantageous methods that further include taking the thermally treated carrier material up on a reel. Support for this amendment can be found in the Application-as-filed on Page 2, lines 4 through 11.

Applicants respectfully submit that this response does not raise new issues, but merely places the above-referenced application either in condition for allowance, or alternatively, in better form for appeal. Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

*The Claimed Invention is Patentable*

*in Light of the Art of Record*

Claims 5 and 6 stand rejected over United States Patent No. 4,569,837 ("US 837") to Suzuki et al. in view of United States Patent Application Publication No. 2001/0006677 ("US 677") to McGinity et al.; United States Patent No. 2,486,258 ("US 258") to Chavannes; United States Patent No. 4,079,106 ("US 106") to Goldsworthy et al., and United States Patent No. 4,622,761 ("US 761") to Barth.

Claims 1, 3, and 7 stand rejected over the foregoing references and further in view of Lerdkanchanaporn et al. (Thermochimica Acta 2000 357-358:71-78) ("Thermochimica") and Lerdkanchanaporn et al. (Journal of Thermal Analysis 1887 49:879-886)("Thermal Analysis").

Claims 1 and 8 over US 837 in view of US 677, US 258, US 106 and further in view of United States Patent No. 4,978,836 (US 836) to Dieudonne et al. and United States Patent No. 5,112,220 ("US 220") to Wimberger et al.

Applicants respectfully submit that none of the cited references teaches or suggests the advantageous synchronized roller coating methods recited within the claims as-amended, and most certainly not such synchronized roller coating methods applying a coating composition heated to approximately 40 to 100 °C, as further recited within the claims as-amended.

Applicants further respectfully reiterate that the cited references simply do not recognize the removal of contaminants that have diffused into a drug, food or cosmetic coating carrier as an issue, much less recommend the claimed thermal treatment temperatures and dwell times to address such diffusion. Consequently, there would have been no motivation to have incorporated an additional thermal treatment, as the problem was unknown. *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008)(non-obviousness of solution to previously unknown problem). US 258 merely notes use of a "buffing brush" with ornamental films, while US 106 notes the cleaning of foam residue from the surface of a wax coated belt.

Accordingly, Applicants respectfully submit that the claimed invention is patentable in light of the cited references, as the cited references do not teach or suggest either the advantageous inventive coating methods within the claims as-amended or the recited decontamination processes associated therewith.

US 837 is directed to pharmaceutical preparations for periodontal disease. (Col. 2, lines 16 – 18). US 837 notes that its medicinal agent is dissolved in polymer, cast and dried. (Col. 5, lines 40 – 45). US 837 generically notes that its compositions may be cast onto a glass plate, metal plate, drum or “endless belt.” (Col. 6, lines 3 – 8). The working examples of US 837 cast the medicinal compositions onto a glass plate or subject them to compression molding. (Col. 6, line 53 through Col. 10, line 55).

US 837, merely noting polymer dissolution and casting, does not teach or suggest advantageous methods including heating a drug, food or cosmetic-containing coating to approximately 40 to 100 °C, much less the application of such heated coating onto a carrier material via synchronized rollers, and most certainly not subjecting the resulting contaminated carrier material to a thermal decontamination step, as reflected in the claims as-amended.

US 677 is merely directed to extruded effervescent films having a controlled rate of disintegration. (Para. 0001). The impetus of US 677 is that extrusion allows for extremely short exposure times to elevated temperatures than batchwise hot-melt methods, and further does not require solvents. (Para. 0025). The films of US 677 are formed by extruding the effervescent mixture and either rolling the resulting film extrudant directly into a tape or cutting it into pieces. (Para. 0095).

US 677, solely directed to extruded films, does not teach or suggest advantageous methods including heating a drug, food or cosmetic-containing coating to approximately 40 to 100 °C, much less the application of such heated coating onto a carrier material via synchronized rollers, and most certainly not subjecting the resulting contaminated carrier material to a thermal decontamination step, as reflected in the claims as-amended.

US 258 is directed to films having an embedded design. (Col. 1, lines 23 – 30). An “engraved roller” applies an initial “film-forming substance,” which may contain solvent such as methyl ethyl ketone, to a carrier. (Col. 3, line 48 – Col. 4, line 2). The carrier bearing the design imparted by the engraved roll is then passed through a coating apparatus that applies a further layer of film-forming substance over the design. (Col. 4, lines 58 – 60). The films of US 258 are formed on a “continuous carrier” that has been coated so that “it will not be attacked” by components within the coating. (Col. 3, lines 29 – 37). US 258 expressly teaches cleaning of its carrier surface with a driven buffing brush. (Col. 6, lines 52 – 62).

US 258, generically noting the application of film-forming substances, does not teach or suggest advantageous methods including heating a drug, food or cosmetic-containing coating to approximately 40 to 100 °C, much less the application of such heated coating onto a carrier material via synchronized rollers, and most certainly not subjecting the resulting contaminated carrier material to a thermal decontamination step, as reflected in the claims as-amended.

Applicants respectfully reiterate that US 106 is directed to the continuous fabrication of polyurethane foam insulation. (Col. 1, lines 55 – 60). US 106 applies polymer that has been metered and mixed together via a “standard” machine to three dimensional filaments disposed on the surface of a belt which has been coated with a wax or an equivalent release agent. (Col. 2, lines 25 - 28 and 44 – 45). After curing sufficiently, the foamed material is “cut” from the belt. (Col. 2, lines 39 – 41). After cutting the cured/dried material from the belt, the belt is “cleaned” and subsequently re-coated with a wax or release agent. (Col. 2, lines 43 – 47). Suitable cleaning methods include mechanical cleaning and solvent cleaning. (Col. 2, line 44).

US 106, generically noting the metering and mixing of foam, does not teach or suggest advantageous methods including heating a drug, food or cosmetic-containing coating to approximately 40 to 100 °C, much less the application of such heated coating onto a carrier material via synchronized rollers, and most certainly not subjecting the resulting contaminated carrier material to a thermal decontamination step, as reflected in the claims as-amended.

US 761 is directed to particular dryers that have been contaminated by volatilized medicinal residues. (Col. 1, lines 33 – 38). US 761 is particularly directed to TTS dryer systems that avoid “contamination from residues of previous charges” and prevent the escape of substances into the atmosphere. (Col. 1, lines 57 – 64). The dryers of US 761 have cup-shaped, rounded wall elements enabling rapid disassembly for cleaning. (Col. 2, lines 31 – 49). A “self-supporting” sheet of material is guided through the dryer. (Col. 4, lines 35 – 40). US 761 further teaches that solvents and medicinal residues escaping as the sheet of material is dried may be burned. (Col. 3, lines 49 – 51).

US 761, solely directed to particular dryers, does not teach or suggest advantageous methods including heating a drug, food or cosmetic-containing coating to approximately 40 to 100 °C, much less the application of such heated coating onto a carrier material via synchronized rollers, and most certainly not subjecting the resulting contaminated carrier material to a thermal decontamination step, as reflected in the claims as-amended.

Applicants respectfully submit that there would have been no motivation to have combined US 837, US 677, US 258, US 106 and US 761. Applicants further respectfully reiterate that the arts of cast films, hot melt films, foam insulation, decorative films and transdermal therapeutic devices are incredibly divergent.

However, even if the foregoing references were combined (which Applicants did not do), the claimed invention would not have resulted.

Particularly, the cited references simply do not teach or suggest advantageous methods including heating a drug, food or cosmetic-containing coating to approximately 40 to 100 °C, much less the application of such heated coating onto a carrier material via synchronized rollers, and most certainly not subjecting the resulting contaminated carrier material to a thermal decontamination step, as reflected in the claims as-amended.

The primary reference merely generically notes polymer dissolution and casting. The remainder of the cited references, directed to altogether different processes, such as extrusion, foam formation and the like, do not cure the deficiencies in the primary reference.

Nor do the references teach or suggest such methods further comprising taking up the thermally treated carrier material on a reel, as recited in newly added Claims 9 and 10.

Applicants thus respectfully submit that the claimed invention is patentable in light of US 837, US 677, US 258, US 106 and US 761, considered either alone or in any combination.

Claims 1, 3, and 7 are likewise patentable in further view of Thermochemica and Thermal Analysis.

Thermochemica merely profiles the evaporation behavior of ibuprofen between its melting point and boiling point. Thermal Analysis studies the effect of starch on the evaporation onset temperature.

Thermochemica and Thermal Analysis, both directed to evaporative studies, thus do not teach or suggest advantageous methods including heating a drug, food or cosmetic-containing coating to approximately 40 to 100 °C, much less the application of such heated coating onto a carrier material via synchronized rollers, and most certainly not subjecting the resulting contaminated carrier material to a thermal decontamination step, as reflected in the claims as-amended.

Applicants respectfully submit that the claimed invention is patentable in light of US 837, US 677, US 258, US 106, and US 761, based upon the reasoning provided above.

Applicants respectfully submit that there would have been no motivation to have combined US 837, US 677, US 258, US 106, US 761, Thermochemica and Thermal Analysis. Applicants further respectfully reiterate that the arts of cast films, extruded films, foam insulation, decorative films, transdermal therapeutic devices and evaporative studies are incredibly divergent.

However, even if the foregoing references were combined (which Applicants did not do), the claimed invention would not have resulted.

Particularly, the cited references simply do not teach or suggest advantageous methods that include heating a drug, food or cosmetic-containing coating to approximately 40 to 100 °C, much less the application of such heated coating onto carrier material via synchronized rollers, and most certainly not subjecting the resulting contaminated carrier material to a thermal decontamination step, as reflected in the claims as-amended. The primary reference merely generically notes polymer dissolution and casting. The remainder of the cited references, directed to altogether different processes, do not cure the deficiencies in the primary reference.

Nor does the combination of references teach or suggest such methods further comprising taking up the thermally treated carrier material on a reel, as recited in newly added Claims 9 and 10.

Applicants thus respectfully submit that the claimed invention is patentable in light of US 837, US 677, US 258, US 106 and US 761, Thermochemica and Thermal Analysis considered either alone or in any combination.

Claims 1 and 8 are similarly patentable in further light of US 836 and US 220.

US 836 is directed to continuous ovens for producing printed circuit boards that include a conveying device that carries the printed circuit board through the oven in a defined plane such that structural changes involved do not strongly affect the thermal conditions in the oven. (Col. 1, lines 61 – 66). The ovens of US 836 include electrical infrared heat radiators for the thermal treatment of plate-like components and a conveying device having two synchronously driven, continuous drive bands. (Col. 2, lines 60 – 65).

US 220 is solely directed to air floatation driers for graphic arts that use solvent-laden air as their sole or primary heat source in generating high drying temperatures. (Col. 1, lines 14 – 19 and Col. 2, lines 45 - 51). US 220's driers are intended to dry ink on paper using a raw gas burner. (Col. 6, lines 1 – 6 and 20 - 23). US 220 expressly notes dryer temperatures of up to 500 °F (i.e. 260 °C) as suitable. (Col. 6, lines 6 – 7). As correctly noted by the Examiner, US 220 is altogether silent as to treatment duration.

US 836 and US 220, respectively directed to ovens and driers, do not teach or suggest advantageous methods including heating a drug, food or cosmetic-containing coating to approximately 40 to 100 °C, much less the application of such heated coating onto a carrier material via synchronized rollers, and most certainly not subjecting the resulting contaminated carrier material to a thermal decontamination step, as reflected in the claims as-amended.

Nor does the combination teach or suggest such methods further comprising taking up the thermally treated carrier material on a reel, as recited in newly added Claims 9 and 10.

Applicants respectfully reiterate that the claimed invention is patentable in light of US 837, US 677, US 258, US 106, and US 761, based upon the reasoning provided above.



Applicants respectfully submit that there would have been no motivation to have combined US 837, US 677, US 258, US 106, US 761, US 220 and US 839. Applicants further respectfully reiterate that the arts of cast films, extruded films, foam insulation, decorative films, transdermal therapeutic devices, driers and ovens are incredibly divergent.

However, even if the foregoing references were combined (which Applicants did not do), the claimed invention would not have resulted.

Particularly, the cited references simply do not teach or suggest advantageous methods including heating a drug, food or cosmetic-containing coating to approximately 40 to 100 °C, much less the application of such heated coating onto a carrier material via synchronized rollers, and most certainly not subjecting the resulting contaminated carrier material to a thermal decontamination step, as reflected in the claims as-amended. The primary reference merely generically notes polymer dissolution and casting. The remainder of the cited references do not cure the deficiencies in the primary reference.

Nor does the combination teach or suggest such methods further comprising taking up the thermally treated carrier material on a reel, as recited in newly added Claims 9 and 10.

Applicants thus respectfully submit that the claimed invention is similarly patentable in light of US 837, US 677, US 258, US 106, US 761, US 836 and US 220 considered either alone or in any combination.

### **CONCLUSION**

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1, 3 and 5 through 10 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

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